

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

| | |
|--------------|-------------|
| DUE DATE: | 27-MAY-2006 |
| FORMALITIES: | C.N. RPL |
| PAT. OFF: | A.K.✓ |
| PCTB | 30/3/06 |
| CASE NO: | PU0406-PCT |

To:

Amersham Biosciences AB,
Patent Department
Björkgatan 30
SE-751 84 Uppsala
Sweden

RECEIVED
2006-03-30
U-APD

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

| | | | |
|---|--|-------------------------------------|--|
| Applicant's or agent's file reference PU0406-PCT ✓ | | Date of mailing (day/month/year) | 28-03-2006 |
| International application No. PCT/SE2005/000292 ✓ | International filing date (day/month/year) 24-02-2005 ✓ | REPLY DUE | within 60 days from the above date of mailing |
| Priority date (day/month/year) 27-02-2004 ✓ | | | |
| International Patent Classification (IPC) or both national classification and IPC See Supplemental Box | | | |
| Applicant AMERSHAM BIOSCIENCES AB et al | | | |

- ☒ The written opinion established by the International Searching Authority:
☒ is ☐ is not
considered to be a written opinion of the International Preliminary Examining Authority.
- This second (first, etc.) opinion contains indications relating to the following items:
 - ☒ Box No. I Basis of the opinion
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application
- The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 27-06-2006

Name and mailing address of the IPEA/SE
Patent- och registreringsverket
Box 5055
S-102 42 STOCKHOLM
Facsimile No. 46 8 667 72 88

Authorized officer

Patrick Andersson/MP
Telephone No. 46 8 782 25 00

Form PCT/IPEA/408 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

International application No.

PCT/SE2005/000292

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Cover sheet**

International patent classification (IPC)

B01J 39/04 (2006.01)

B01D 15/32 (2006.01)

B01D 15/36 (2006.01)

C07K 16/06 (2006.01)

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SE2005/000292

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:



the international application in the language in which it was filed



a translation of the international application into _____,
which is the language of a translation furnished for the purposes of:



international search (Rules 12.3(a) and 23.1(b))



publication of the international application (Rule 12.4(a))



international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this opinion has been established on the basis of (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*):



the international application as originally filed/furnished



the description:

pages _____ as originally filed/furnished

pages _____ received by this Authority on _____

pages _____ received by this Authority on _____



the claims:

pages _____ as originally filed/furnished

pages _____ as amended (together with any statement) under Article 19

pages _____ received by this Authority on _____

pages _____ received by this Authority on _____



the drawings:

pages _____ as originally filed/furnished

pages _____ received by this Authority on _____

pages _____ received by this Authority on _____



a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing (*specify*): _____



any table(s) related to the sequence listing (*specify*): _____

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing (*specify*): _____



any table(s) related to the sequence listing (*specify*): _____

**WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

International application No.

PCT/SE2005/000292

Box No. V Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--------|----------------------|
| Novelty (N) | Claims | _____ |
| | Claims | <u>1-3, 6-8 (no)</u> |
| Inventive step (IS) | Claims | _____ |
| | Claims | <u>1-12 (no)</u> |
| Industrial applicability (IA) | Claims | _____ |
| | Claims | _____ |

2. Citations and explanations:

The following documents are considered relevant:

D1) Johansson B-L, "Preparation and characterization of prototypes for multimodal separation aimed for capture of positively charged biomolecules at high-salt conditions", 2003, vol 1016 page 35-49 Journal of Chromatography A.

D2) WO9710887

D3) EP0345649

D1 and D2 disclose a process for purifying antibodies using a multi-modal separation material which is a cation-exchange resin with aromatic ring systems where the ring-forming atoms can be carbon, sulphur or oxygen, see e.g. table 2, figure 3 of D1.

In D1, it is stated that the resin should be tested for capture proteins from different feedstocks.

Consequently, the subject matter of claims 1-3 and 6-8 is previously known and lacks novelty.

Document D2 is considered to represent the closest prior art. The invention according to claims 4-5 and 9-12 differs from the process in D2 in that the solution from a previous protein-A purification step uses a chromatographic resin with a multimodal ligand.

Consequently, with the background of D2, the problem solved by the present application is to design an alternative process to purify antibodies.

.../...

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SE2005/000292

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

The problem with leakage from protein-A columns is well known in the art. Moreover, it is common to combine protein-A chromatography with other chromatographic steps.

To solve the problem in D2 using another chromatographic step known to be used for antibody purification, such as the one in D1, seems to be obvious to a person skilled in the art in the absence of an unforeseeable advantage with the method used. Consequently, the invention according to claims 4-5 and 9-12 lacks an inventive step.